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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,072

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Ilga Winicov

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,072	Applicant(s) WINICOV, ILGA	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>92105,8706,32207,11408,11708</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to because the details in Figures 5-8 are not discernable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 1, 2, 6, 7 and 8 are objected to because of the following informalities: nucleotides are not ordinarily said to “encode” a promoter, since a promoter comprises nucleotides. Appropriate correction is required.

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Claim 1 is objected to because of the following informalities: nucleotides do not comprise “a gene”, since a gene comprises nucleotides. Appropriate correction is required.

Claim 2 is objected to because of the following informalities: nucleotides are not ordinarily said to “encode” a ribosomal binding site, since a ribosomal binding site comprises nucleotides. Appropriate correction is required.

Claims 2, 6, 7 and 8 are objected to because of the following informalities: the phrase “protein nucleotides” is confusing, since nucleotides encode proteins, and proteins comprise amino acids. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims require the presence or use of a genus of nucleotides of unspecified structure encoding a promoter designated “MsPRP2” or a fragment thereof. The claims also require the presence of a genus of nucleotides of unspecified structure encoding a genus of transcription factors of unspecified structure designated “Alfin1”.

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With respect to a promoter region designated “MsPRP2”, the specification describes a single nucleotide sequence of SEQ ID NO:1 (Figure 2).

With respect to nucleotides encoding a transcription factor designated “Alfin1”, the specification does not describe the structure of any particular nucleotide sequence.

The Federal Circuit has clarified the application of the written description requirement to nucleotide sequences. The court stated that “A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has also affirmed the PTO's applicable standard for determining compliance with the written description requirement, quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, “Written Description” Requirement, 66 Fed. Reg. 1099, 1106, where it is set forth that the written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (CAFC 2002)

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus of nucleotide sequences that have the

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designation “MsPRP2”, nor the structural features unique to the genus that are correlated with their function as promoters.

In the instant case Applicant also has not described a representative number of species falling within the scope of the claimed genus of nucleotide sequences that have the designation “Alfin1”, nor the structural features unique to the genus that are correlated with their ability to encode proteins that function as transcription factors.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite due to the recitation of “MsPRP2” and “Alfin1”. It is unclear which promoters and which transcription factors are encompassed by the claims, since an acronym or a name can have multiple meanings.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps that result in the bioremediation of the field.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Winicov (WO 99/53016, published October 21, 1999).

The claims are drawn to an expression cassette capable of directing heterologous protein expression in plant roots, comprising a) nucleotides encoding MsPRP2 promoter or a fragment thereof, including a promoter or fragment comprising a portion of SEQ ID NO : 1; and b) nucleotides comprising a gene for a heterologous protein, operably linked to the MsPRP2 nucleotides.

Winicov teaches an expression cassette capable of directing heterologous protein expression in plant roots comprising an MsPRP2 promoter or a fragment thereof and “other genes” operably linked to the MsPRP2 promoter (paragraph spanning pages 19-20). The promoter or fragment thereof comprises a portion of SEQ ID NO : 1; see sequence alignment below. The “other genes” are genes for a “heterologous” protein because “other” genes are not the MsPRP2 gene from which the promoter was obtained.

```

RESULT 2
AAZ34539
ID   AAZ34539 standard; DNA; 1612 BP.
XX
AC   AAZ34539;
XX
DT   01-FEB-2000 (first entry)
XX
DE   Alfalfa salt inducible MsPRP2 gene promoter region.
XX
KW   MsPRP2 gene; promoter; Alfin1; transcription factor; alfalfa;
KW   salt tolerance; stress tolerance; transgenic plant; root; ds.
XX
OS   Medicago sativa.
XX
FH   Key          Location/Qualifiers
FT   protein_bind complement(718..727)
FT               /*tag= a
FT               /note= "Alfin1 binding site"
FT   protein_bind complement(778..786)
FT               /*tag= b
FT               /note= "Alfin1 binding site"
FT   protein_bind complement(1034..1049)
FT               /*tag= c
FT               /note= "Alfin1 binding site"
FT   protein_bind complement(1079..1087)
FT               /*tag= d
FT               /note= "Alfin1 binding site"

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```
FT protein_bind complement(1155..1160)
FT /*tag= e
FT /note= "Alfin1 binding site"
FT protein_bind 1251..1261
FT /*tag= f
FT /note= "Alfin1 binding site"
FT CAAT_signal 1449..1453
FT /*tag= g
FT TATA_signal 1478..1483
FT /*tag= h
FT CDS 1553..1612
FT /*tag= i
FT /partial
FT /note= "5' end of coding sequence"
XX
PN WO9953016-A2.
XX
PD 21-OCT-1999.
XX
PF 08-APR-1999; 99WO-US007902.
XX
PR 09-APR-1998; 98US-0081348P.
PR 07-APR-1999; 99US-0128083P.
XX
PA (UYAR-) UNIV ARIZONA STATE.
XX
PI Winicov I;
XX
DR WPI; 2000-013097/01.
XX
PT Producing novel transgenic plants tolerant to a wide variety of biotic
PT and abiotic stress conditions.
XX
PS Claim 13; Fig 3; 21pp; English.
XX
CC This is the nucleotide sequence of the promoter region of the root-
CC directed salt-inducible MsPRP2 gene of alfalfa. The promoter includes
CC potential sites for binding to Alfin1 (see AAY32143), a newly identified
CC root-specific transcription factor of alfalfa that is associated with
CC salt tolerance. The full or partial MsPRP2 promoter sequence can be used
CC by itself or in conjunction with other promoter sequence elements to
CC construct new composite promoter regulatory sequences that would give
CC root-specific and/or Alfin1 protein regulated expression to other genes
CC transferred into plants. The Alfin1 protein binding sequences could also
CC be used, as concatenates or in conjunction with other promoter sequence
CC elements, to construct new composite promoter regulatory sequences. It is
CC believed the introduction of Alfin1 binding sites in appropriate promoter
CC contexts could lead to regulation of additional genes by Alfin1. The
CC invention may be used to manipulate plant growth and to enhance plant
CC tolerance to a wide variety of biotic and abiotic stress conditions,
CC including salt
XX
SQ Sequence 1612 BP; 561 A; 274 C; 214 G; 563 T; 0 U; 0 Other;

Query Match 99.9%; Score 1553.4; DB 1; Length 1612;
Best Local Similarity 99.9%; Pred. No. 2.5e-228;
Matches 1554; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 1 TTTTATAAATATTTAAGCTTGATAATAATTTTGCATCTATATATAAGCCACTACCAATT 60
Db 1 TTTTATAAATATTTAAGCTTGATAATAATTTTGCATCTATATATAAGCCACTACCAATT 60
Qy 61 TAAATATATATATATATATATATATATATATATATAATAATTTTATTATATTTAT 120
Db 61 TAAATATATATATATATATATATATATATATATATAATAATTTTATTATATTTAT 120
Qy 121 TACGTTGATGGTAAAAAATAAATAATTTGTTACCATTAAAAAGTCATAAATATAGTA 180
Db 121 TACGTTGATGGTAAAAAATAAATAATTTGTTACCATTAAAAAGTCATAAATATAGTA 180
Qy 181 CAATCCAACCCCTTGAGAGGTTAATGTGTGTGCGGATTTTCTAGATAAAACAAGGTGCCAT 240
Db 181 CAATCCAACCCCTTGAGAGGTTAATGTGTGTGCGGATTTTCTAGATAAAACAAGGTGCCAT 240
Qy 241 TCACGATTCTTCTTGGTGCAGCTTGGAGAACCCTATCCTGGGCTTGAAGATTACTTCT 300
Db 241 TCACGATTCTTCTTGGTGCAGCTTGGAGAACCCTATCCTGGGCTTGAAGATTACTTCT 300
Qy 301 TGTGTGATGCTTCTAGAGTACAGCTCCTTAAGGCTGTAGTCTAGTTTTTTTTTTCATCCTT 360
Db 301 TGTGTGATGCTTCTAGAGTACAGCTCCTTAAGGCTGTAGTCTAGTTTTTTTTTTCATCCTT 360
Qy 361 CCTACCAAAAAAAAAAAGTCATAAATATAGTTTATACATATAACTTTAATAAAAAATAAA 420
Db 361 CCTACCAAAAAAAAAAAGTCATAAATATAGTTTATACATATAACTTTAATAAAAAATAAA 420
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Qy	421	AAAATTTTCATCCCTAAAAACATAGTAGAAATTTTCATAAAAAAATATTGTTTATAATTTA	480
Db	421	AAAATTTTCATCCCTAAAAACATAGTAGAAATTTTCATAAAAAAATATTGTTTATAATTTA	480
Qy	481	CATGCCGTTACGGTAAAAAATGGATAAATTTGGGTATGGAGTACTAGTAATTAATAAGGTT	540
Db	481	CATGCCGTTACGGTAAAAAATGGATAAATTTGGGTATGGAGTACTAGTAATTAATAAGGTT	540
Qy	541	CATTGGTTAAAAAACTAAAAAATAATTTCTCTCTGATTATATGAAATGACATTTTTT	600
Db	541	CATTGGTTAAAAAACTAAAAAATAATTTCTCTCTGATTATATGAAATGACATTTTTT	600
Qy	601	TGGAACATGAAGGGTATTGATTTTTTACCACCTTTTACACCTTTCAAAGCCATTCAAGGAT	660
Db	601	TGGAACATGAAGGGTATTGATTTTTTACCACCTTTTACACCTTTCAAAGCCATTCAAGGAT	660
Qy	661	GAATATAGATTTTTTGGGCGCATCAAAACACAAGAATCATTACGATAACATGCTTTGGAACAC	720
Db	661	GAATATAGATTTTTTGGGCGCATCAAAACACAAGAATCATTACGATAACATGCTTTGGAACAC	720
Qy	721	ACACATGCTTAAATTAATGGTTGGAGTATCAAATTTTAAAAATATTGTTGTCAATACATAC	780
Db	721	ACACATGCTTAAATTAATGGTTGGAGTATCAAATTTTAAAAATATTGTTGTCAATACATAC	780
Qy	781	CCCGTCAATCTTCTTTTTTTTACCCAATAAACATTGAAATGTTGCTCTTTTCGTTAAGCA	840
Db	781	CCCGTCAATCTTCTTTTTTTTACCCAATAAACATTGAAATGTTGCTCTTTTCGTTAAGCA	840
Qy	841	TAAAAACATCAAAGTCTAGCAAAATGTTGTTTTTGCATGACACATTTTCATATAGTTTAA	900
Db	841	TAAAAACATCAAAGTCTAGCAAAATGTTGTTTTTGCATGACACATTTTCATATAGTTTAA	900
Qy	901	AGGATGCATGATTTCGATTACAAAAACAAAATACTAATAATTTAGCACAAAGTTTAAAGC	960
Db	901	AGGATGCATGATTTCGATTACAAAAACAAAATACTAATAATTTAGCACAAAGTTTAAAGC	960
Qy	961	AAGATTATAAAGCTTCATAGCATGTGGATATTTCATTAGAAAATATAGATTAGATTGCCCC	1020
Db	961	AAGATTATAAAGCTTCATAGCATGTGGATATTTCATTAGAAAATATAGATTAGATTGCCCC	1020
Qy	1021	TTTCATCACGGGCTTAACAGCACCACTTGTCTACTACATGTCAAAAATGTCCTCTAGTACA	1080
Db	1021	TTTCATCACGGGCTTAACAGCACCACTTGTCTACTACATGTCAAAAATGTCCTCTAGTACA	1080
Qy	1081	GCACCGCTTTTTACTTGGATTCCCCTTGTCCATGCATGAAAAAATCAAAACAATTTTGG	1140
Db	1081	GCACCGCTTTTTACTTGGATTCCCCTTGTCCATGCATGAAAAAATCAAAACAATTTTGG	1140
Qy	1141	ACACACAAACTTGCCCCCACTTTCCTTTTTCTTTCTGCCCTAGTTTGTGAGACTCATA	1200
Db	1141	ACACACAAACTTGCCCCCACTTTCCTTTTTCTTTCTGCCCTAGTTTGTGAGACTCATA	1200
Qy	1201	TTGATCAAATTTGGCTATGAATTCAAACAAAAAATTCACCTTACCATTGCATGTGTGGG	1260
Db	1201	TTGATCAAATTTGGCTATGAATTCAAACAAAAAATTCACCTTACCATTGCATGTGTGGG	1260
Qy	1261	GCCACATATAAATCCATGAAGGATTTCAATGTCCATCCAAGTCAATGATTCAACATATA	1320
Db	1261	GCCACATATAAATCCATGAAGGATTTCAATGTCCATCCAAGTCAATGATTGAACATATA	1320
Qy	1321	TAACATTGAATAATTTAATTCCAATTTGCAGTATTATGATTAGATTGATTGCTGCAATA	1380
Db	1321	TAACATTGAATAATTTAATTCCAATTTGCAGTATTATGATTAGATTGATTGCTGCAATA	1380
Qy	1381	CGTCCGTGAATGTGATCACTCAGGAGAAAGAGGTATCAAAATTTCAAGGTATTTTATTT	1440
Db	1381	CGTCCGTGAATGTGATCACTCAGGAGAAAGAGGTATCAAAATTTCAAGGTATTTTATTT	1440
Qy	1441	ATTTTAAACAAATAAAATTTCAAGGCTCTTGTTCCACATATAAACCTCCTCACTCACACCC	1500
Db	1441	ATTTTAAACAAATAAAATTTCAAGGCTCTTGTTCCACATATAAACCTCCTCACTCACACCC	1500
Qy	1501	AATTCTCTTAAGTGTATGACTTTCATAGTACACTACACTCTTCTTTGAAACATG	1555
Db	1501	AATTCTCTTAAGTGTATGACTTTCATAGTACACTACACTCTTCTTTGAAACATG	1555

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winicov (WO 99/53016, published October 21, 1999).

The claims are drawn to an expression cassette capable of directing heterologous protein expression in plant roots, comprising a) nucleotides encoding MsPRP2 promoter or a fragment thereof, said promoter or fragment comprising a portion of SEQ ID NO : 1; and b) nucleotides comprising a gene for a heterologous protein, operably linked to the MsPRP2 nucleotides, said expression cassette further comprising nucleotides encoding transcription factor Alfin1, the Alfin1 nucleotides being operably linked to another promoter such that the other promoter causes the transcription factor Alfin1 to be overexpressed.

The claims are also drawn to a plant transfected with the expression cassette of claim 1, and a plant cell culture transfected with the expression cassette of claim 1.

The claims are additionally drawn to a method of producing a protein recombinantly in plant cells, the method comprising: a. growing plant cells which have been transfected with an expression cassette comprising: i. nucleotides encoding a promoter of MsPRP2 or a fragment thereof, and ii. nucleotides encoding the protein, said protein nucleotides being operably linked to the MsPRP2 promoter nucleotides, and b. growing the transformed cells, during which the transformed cells produce the protein.

Winicov teaches an expression cassette capable of directing heterologous protein expression in plant roots comprising an MsPRP2 promoter or a fragment thereof and “other genes” operably linked to the MsPRP2 promoter (paragraph spanning pages 19-20). The promoter or fragment thereof comprises a portion of SEQ ID NO : 1. The “other genes” are genes for a “heterologous” protein because “other” genes are not the MsPRP2 gene from which the promoter was obtained.

While Winicov does not exemplify plant and plant cell cultures transfected with the expression cassette of claim 1, Winicov teaches that such plants and plant cell cultures can be made (page 4; page 24 claims 9-11). Winicov also teaches the production of a recombinant protein in plant cells, because expression of the Alfin1 coding sequence in a sense orientation results in Alfin1 protein overexpression (page 11 last full paragraph). Winicov additionally teaches that the MsPRP2 promoter comprises the elements necessary for promoter function (Figure 3). Winicov further teaches the production of alfalfa plants transformed with expression cassettes that comprise the Alfin1 coding sequence under the control of a CaMV 35S promoter (pages 11-17). Winicov also teaches that expression of native MsPRP2 gene is enhanced in transgenic plants that overexpress Alfin1, and that the MsPrP2 promoter sequence contains Alfin1 binding sites (page 11 last full paragraph; page 8 Table 2).

Given the teachings of Winicov that an expression cassette comprising the MsPRP2 promoter and a gene for a heterologous protein can be made, that an expression cassette comprising another promoter and an Alfin1 coding sequence can be made, that expression of native MsPRP2 gene is enhanced in transgenic plants that overexpress Alfin1, and that the MsPrP2 promoter sequence contains Alfin1 binding sites, it would

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have been *prima facie* obvious to one skilled in the art at the time the invention was made to make an expression cassette comprising both the MsPRP2 promoter and a gene for a heterologous protein, and another promoter and an Alfin1 coding sequence. One skilled in the art would have been motivated to do so in order to increase the expression of the heterologous protein from the MsPRP2 promoter. One skilled in the art would have had a reasonable expectation of success, given the success of Winicov in making transgenic plants that overexpress Alfin1, and given that the MsPRP2 promoter comprises both the elements necessary for promoter function and contains Alfin1 binding sites.

Additionally, given the teachings of Winicov that plants and plant cells can be transfected with the expression cassette, and that recombinant Alfin1 protein can be produced in transgenic plants and plant cells, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to make plants and plant cells transfected with the expression cassette of claim 1, and to produce a recombinant protein in such plant cells. One skilled in the art would have been motivated to do so in order to express in the plants cells and plants a heterologous protein from the MsPRP2 promoter. One skilled in the art would have had a reasonable expectation of success, given the success of Winicov in making transgenic plants that overexpress Alfin1, and given that the MsPRP2 promoter comprises both the elements necessary for promoter function and contains Alfin1 binding sites.

Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

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Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winicov (WO 99/53016, published October 21, 1999) in view of Lee et al. (U.S. Patent No. 6,020,169, issued February 1, 2000).

Claim 7 is drawn to a method of producing a secreted protein from plant cells, the method comprising: a. growing plant cells which have been transfected with an expression cassette comprising: i. nucleotides encoding a promoter of MsPRP2 or a fragment thereof; ii. nucleotides encoding a secretion signal which are downstream from the MsPRP2 promoter or fragment thereof, and iii. nucleotides encoding the protein, said protein nucleotides being operably linked to the MsPRP2 promoter nucleotides; and b. growing the transformed cells, during which the transformed cells produce the protein.

The teachings of Winicov are set forth above.

Winicov does not teach the production of a secreted protein.

Lee et al. teach the production of secreted proteins in plant cells transformed with an expression cassette comprising a promoter, a sequence encoding a secretion signal peptide, and a protein coding sequence (claims 1-17).

Given the teachings of Winicov that plant cells can be transfected with an expression cassette comprising an MsPRP2 promoter and a protein coding sequence, and that recombinant proteins can be produced in said plant cells, and given the teachings of Lee et al. that recombinant proteins can be produced in and secreted from plant cells transformed with an expression cassette comprising a promoter, a sequence encoding a secretion signal peptide, and a protein coding sequence, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to make plant cells transfected with expression cassette comprising an MsPRP2 promoter, a sequence

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encoding a secretion signal peptide, and a protein coding sequence, and to produce a secreted recombinant protein in such plant cells. One skilled in the art would have been motivated to do so in order to obtain a secreted expressed recombinant protein from the plant cells. One skilled in the art would have had a reasonable expectation of success, given the success of Winicov in making transgenic plants that overexpress Alfin1, given that the MsPRP2 promoter comprises both the elements necessary for promoter function and contains Alfin1 binding sites, and given the success of Lee et al. in producing secreted expressed recombinant proteins in plant cells. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winicov (WO 99/53016, published October 21, 1999) in view of Scheres et al. (U.S. Patent Application Publication No. 2004/0067506, published April 8, 2004).

Claim 8 is drawn to seeds for plants producing a heterologous protein in its roots, the seeds comprising transgenic plant cells which have been transformed with nucleotides encoding a promoter of MsPRP2 or a fragment thereof, nucleotides encoding the protein.

Claim 9 is drawn to a method of bioremediating a field, the method comprising planting the transgenic seeds of claim 8 with or without the secretion signal.

The teachings of Winicov are set forth above. Winicov also implicitly teaches seeds because Winicov teaches seed bearing plants, e.g. alfalfa.

Winicov does not teach field bioremediation.

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Scheres et al. teach the use of transgenic plants for bioremediation, including plants transgenic for an expression cassette comprising a root-specific promoter operably linked to metal-resistance genes (page 7 paragraph [0094] and page 56 claims 1-2).

Given the teachings of Winicov that an expression cassette comprising an MsPRP2 promoter is capable of directing heterologous protein expression in plant roots, and that the production of transgenic plant cells, plants and seed were known to and within the abilities of one skilled in the art at the time of Applicant's invention, and given the teachings of Scheres et al. that transgene expression in roots is useful for phytoremediation techniques, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use seed transgenic for an expression cassette comprising the MsPRP2 promoter and a sequence encoding a heterologous protein for field bioremediation. One skilled in the art would have been motivated to do so in order to express the heterologous protein in the roots of seedlings produced by the transgenic seed. One skilled in the art would have had a reasonable expectation of success, given the success of Winicov in making transgenic plants that overexpress Alfin1, and given that the MsPRP2 promoter comprises both the elements necessary for promoter function and contains Alfin1 binding sites. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,936,708. Although the conflicting claims are not identical, they are not patentably distinct from each other because the isolated Alfalfa MsPRP2 promoter of claim 1 of U.S. Patent No. 6,936,708 comprises a portion of SEQ ID NO:1 of the instant application (see sequence alignment below), and the use of Alfalfa MsPRP2 promoter of claim 1 of U.S. Patent No. 6,936,708 in an expression cassette would have been obvious, including an expression cassette further comprising nucleotides encoding Alfin1. See, e.g., column 13 second full paragraph of U.S. Patent No. 6,936,708.

RESULT 1
US-09-647-841B-1
; Sequence 1, Application US/09647841B
; Patent No. 6936708
; GENERAL INFORMATION:
; APPLICANT: Arizona Board of Regents, acting for and on behalf of Arizona State

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Db      923  AAAACAAAATACTAATAATTCTAGCACAAAGTTTAAAGCAATATTATAAAGCTTCATAGC 982
Qy      982  ATGTGGATATTCATTTAGAAATATAGATTAGATTGCCCCCTTTCATCACGGGTCTAACAGC 1041
          |||
Db      983  ATGTGGATATTCATTTAGAAATATAGATTAGATTGCCCCCTTTCATCACGGGTCTAACAGC 1042
Qy      1042 ACCACTTGTCTACTACATGTCAAAAATGTCCTCTAGTACAGCACCGCTTTTACTTGATTG 1101
          |||
Db      1043 ACCACTTGTCTACTACATGTCAAAAATGTCCTCTAGTACAGCACCGCTTTTACTTGATTG 1102
Qy      1102 CCCTTGTCCATGCATGAAAAAATCAAAACAATATTTGGACACACAAACTTGCCCCCACT 1161
          |||
Db      1103 CCCTTGTCCATGCATGAAAAAATCAAAACAATATTTGGACACACAAACTTGCCCCCACT 1162
Qy      1162 TTCCTTTTTCTTTCTGCCCTAGTTTGTGTTGAGACTCATATTGATCAAATTTGGCTATGAA 1221
          |||
Db      1163 TTCCTTTTTCTTTCTGCCCTAGTTTGTGTTGAGACTCATATTGATCAAATTTGGCTATGAA 1222
Qy      1222 TTCAACAAAAAATTCACCTCTACCCATTGCATGTGTGGGGCCACATATAAATCCATGAA 1281
          |||
Db      1223 TTCAACAAAAAATTCACCTCTACCCATTGCATGTGTGGGGCCACATATAAATCCATGAA 1282
Qy      1282 GGATTTCAATGTCCATCCAAGTCAATGATTCAACATATATAACATTGAATAATTTAATTC 1341
          |||
Db      1283 GGATTTCAATGTCCATCCAAGTCAATGATTCAACATATATAACATTGAATAATTTAATTC 1342
Qy      1342 CAATTGTCAGTATTATGATTAGATTGATTGCTGCAATACGGTCCGTGAATGTGATCACT 1401
          |||
Db      1343 CAATTGTCAGTATTATGATTAGATTGATTGCTGCAATACGGTCCGTGAATGTGATCACT 1402
Qy      1402 CACGAGAAAGAGGTATCAAAATTTCAAGGTATTTTATTTATTTTAAACAAATAAAATTC 1461
          |||
Db      1403 CACGAGAAAGAGGTATCAAAATTTCAAGGTATTTTATTTATTTTAAACAAATAAAATTC 1462
Qy      1462 AAGGCTTGTTCACCATATAAACCTCCTCACTCACACCCAATTCTCTTAAGTGTATGACT 1521
          |||
Db      1463 AAGGCTTGTTCACCATATAAACCTCCTCACTCACACCCAATTCTCTTAAGTGTATGACT 1522
Qy      1522 TCATAGTACACTACACTACTTTCTTTGAAACATG 1555
          |||
Db      1523 TCATAGTACACTACACTACTTTCTTTGAAACATG 1556

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Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC